REMARKS

Claims 13 and 14 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite due to the use of parentheses. Accordingly, the parentheses of claims 13 and 14 have been eliminated.

Claims 8, 12 and 13 have been rejected under 35 U.S.C. § 102(b) as being anticipated by JP 57-105145 A. In rejecting the claims the examiner urges that JP '145 teaches the use of a feed composition that contains xanthophyll and citric acid (a known antioxidant) and thus anticipates the claims. Applicant has carefully considered this rejection but it is most respectfully traversed for the reasons discussed below.

The feed additive disclosed by JP '145 contains fossilized soil of marine organisms, active microorganisms such as streptomyces, acids such as acetic, tartaric and citric acid, and natural pigment, such as carotene and xanthophylls. It is said that with this additive dyspepsia can be cured and the quality of eggs and meat can be improved. For example, it is said that eggs have excellent thickness of shell, color of yolk and viscosity of white. However, the xanthophylls are merely included as a pigment to thereby improve the color of the yolk and the other ingredients are included to have an effect on digestion problems and egg shell quality. These other ingredients are therefore the only recognized active ingredients of the composition (the additive contains fossils = chalk, probiotics = active microorganisms + some acids).

In view of the above, it is clear that JP '145 only teaches that xanthophylls may be included as a pigment additive in a composition which includes other materials as the active ingredient for the treatment of dyspepsia. In short, there is absolutely no disclosure or suggestion which would lead one skilled in the art to conclude that xanthophylls may be selected as an active ingredient and used as an active ingredient in the treatment of dyspepsia. In other words there is absolutely no therapeutic effect taught or suggested by JP '145.

In this regard it is to be noted that claim 8 has been amended to recite that the medicament comprises at least one type of xanthophyll as an active ingredient. Applicant submits that JP '145 does not disclose or suggest the use of a xanthophyll as an active ingredient in the treatment of dyspepsia.

Claims 8-14 have been rejected under 35 U.S.C. § 102(b) as being anticipated by European patent application no. 0770385A1. Applicant has carefully considered this rejection but it is most respectfully traversed for the reasons discussed below.

The EP '385 describes the use of astaxanthin and/or a fatty acid ester thereof as a medicament against stress. On page 5, lines 42-55 and page 6 lines 48- page 7 line 7 it is disclosed that the composition is able to prevent or improve various health disorders caused by stress. It may also be used for mental or physical relaxation or for mental stabilisation. In addition the composition is said to be able to prevent or alleviate decreases in immunological function caused by stress. Further the composition is said to prevent or alleviate gastric and duodenal ulcers brought about by destruction of mucous membrane in the stomach and duodenum caused by stress etc. There is no suggestion of using the composition for non-stress related dyspepsia. Therefore a practitioner who would like to treat or prevent dyspepsia, such as symptoms of heartburn, would not consider administration of a medicament developed for stress.

Claims 8-14 have been rejected under 35 U.S.C. § 102(b) as being anticipated by WO 98/37874. In rejecting the claims the examiner urges that WO '874 teaches a method of treating or preventing inflammation of the gastrointestinal tract caused by *Helicobacter* infection using astaxanthin and therefore anticipates the claims. Applicant has carefully considered this rejection but it is most respectfully traversed for the reasons discussed below.

WO '874 claims an oral preparation comprising at least one type of xantophylles, preferably astaxanthin, for the treatment of inflammation in the mucous membrane of

mammalian gastrointestinal tract caused by a *Helicobacter sp.* infection. It is clear from Table 1 in the WO '874 that the *Helicobacter pylori* bacteria are killed and therefore a man skilled in the art would conclude that astaxanthin has a bacteria-killing effect. The WO '874 is thus limited to inflammatory conditions caused by *Helicobacter sp.* The extension from that disclosure to the assumption that xantophylls, especially astaxanthin, should have an effect against dyspepsia—even at prophylactic treatment —cannot be regarded as obvious for a man skilled in the art.

As disclosed in the present specification under the headline "Background of the invention" the first choice of treatment for temporary and disappearing dyspepsia is ingestion of antacids. In case of *Helicobacter sp.* infection the first choice of treatment is antibiotics. As already explained above, dyspepsia cannot be considered equal to *Helicobacter* infection.

Lastly, claims 8-14 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over JP '145 in view of WO '874. Applicant has carefully considered this rejection but it is most respectfully traversed for the reasons discussed below.

In rejecting the claims the examiner urges that JP '145 teaches the use of xanthophylls to treat dyspepsia. Applicant disagrees. As noted above, JP '145 merely teaches a feed additive for curing dyspepsia which contains xanthophylls only as a pigment, not as an active ingredient as presently recited in claim 8.

The examiner also states that WO '874 teaches the use of astaxanthin to treat infections that cause indigestion. Applicant disagrees. As noted above, WO '874 teaches treatment of inflammation in the mucous membrane in the mammalian gastrointestinal tract caused by an *Helicobacter sp.* infection.

Based on the teaching of WO '874, i.e., that astaxanthin may kill *Helicobacter* bacteria, one skilled in the art would not reasonably expect that astaxanthin could

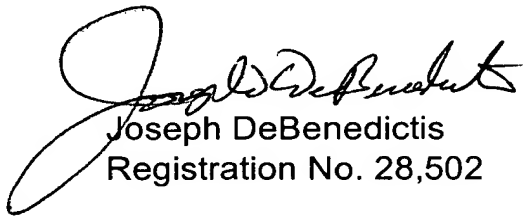
beneficially be used as the xanthophyll, i.e., as the pigment required by JP '145. Therefore, one skilled in the art would not have been motivated to use astaxanthin to treat dyspepsia in the method taught by JP '145.

In view of the above arguments and amendment to the claims, applicant respectfully requests reconsideration and allowance of all the claims which are currently pending in the application.

Attached hereto is a marked-up version of changes made to the application by this amendment. The attachment is captioned "Version with Markings to Show Changes Made".

Respectfully submitted,

Date: January 21, 2003



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The below claims are amended as follows:

8. (Amended) [Method] A method of prophylactic and/or therapeutic treatment of dyspepsia in an individual, which comprises administration to said individual of an dyspepsia-alleviating amount of a medicament comprising as an active ingredient at least one type of [xanthophylls] xanthophyll.

9. (Amended) [Method] The method according to claim 8, wherein the xanthophyll is astaxanthin.

10. (Amended) [Method] The method according to claim 9, wherein the astaxanthin is in a form esterified with fatty acids.

11. (Amended) [Method] The method according to claim 10, wherein the astaxanthin in esterified form is provided in the form of algal meal prepared from a culture of the alga *Haematococcus sp.*

12. (Amended) [Method] The method according claim 8, wherein the medicament further comprises carbohydrate structures.

13. (Amended) [Method] The method according to claim 8, wherein the medicament further comprises [(a)] a different [antioxidant(s)] antioxidant.

14. (Amended) [Method] The method according to claim 8, wherein the dyspepsia-alleviating amount of the medicament comprises [xanthophyll(s)] said xanthophyll in the range of 0.05 to 1 mg per kg body weight of the individual.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: AKE LINDE

SERIAL NO.: 09/463,958

FILED: Jan. 17, 2002

FOR: Treatment of Dyspepsia

GROUP ART UNIT: 1654

EXAMINER: S.D. Coe

ATTY. REFERENCE: LING3003JDB

THE COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Sir:

Transmitted herewith is a communication/amendment in the above-identified application.

☐ Small entity status under *37 CFR 1.9* and *1.27* is claimed.

☒ No additional fee is required.

The fee, if any, has been calculated as shown below:

Fee Basis	Number of Claims After Amendment	Highest Number Previously Paid For	Extra Claims	Small Entity	Full Fee
Total Claims	9	- 20 [1]	= 0 [3]	× $ 9 =	× $ 18 =
Independent Claims	1	- 3 [2]	= 0 [3]	× $ 42 =	× $ 84 =
☐ First Presentation of Proper Multiple Dependent Claim				+ $140 =	+ $280 =
			TOTAL		

[1] If less than 20 enter **20**. [2] If less than 3 enter **3**. [3] If less than 0 enter **0**.

☐ Please charge my **Deposit Account Number 02-0200** in the amount of $_____. A duplicate copy of this sheet is attached.

☐ A check in the amount of $_____ is attached.

☒ The Commissioner is hereby authorized to charge any additional fees associated with this communication, including fees due under *37 CFR 1.16* and *37 CFR 1.17* or credit any overpayment to **Deposit Account Number 02-0200**. A duplicate copy of this sheet is attached.

☐ Also enclosed is/are:

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23364
PATENT TRADEMARK OFFICE

Respectfully submitted,

DATE: January 21, 2003

Joseph DeBenedictis
Attorney for Applicant
Registration Number: 28,502

PATENT

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